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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,994	12/03/2003	Kedar R. Belhe	47563.0015	4512
57600	7590	10/12/2007		
HOLLAND & HART LLP P.O. Box 11583 60 E. South Temple, Suite 2000 Salt Lake City, UT 84110			EXAMINER WOO, JULIAN W	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 10/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/726,994

Applicant(s)

BELHE ET AL.

Examiner

Julian W. Woo

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 21-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-7, 11-18, and 21-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Modesitt et al. (6,136,010). Modesitt et al. disclose, at least in figures 4-5, 11A-11E, and 13 and in col. 10, line 18 to col. 11, line 29; a vascular closure device and a method with the device for closing a vascular opening; where the device includes first and second needles (38, 38'), a suture (34), a snare (42 and/or 40 and 74—see fig. 4) configured to grasp suture (i.e., element 42 itself can snag suture or can snag element 40, which is connected to suture; or element 40 itself grasps suture), a pre-tied knot (80), a handle (20), and an anchor (24) configured to extend through an opening in a blood vessel, the anchor being configured to move between a contracted configuration where the anchor is sized to fit through the opening in the blood vessel and an expanded configuration where the anchor is too large to fit through the opening in the blood vessel; where the first and second needles extend outward and away from a sheath (12) at an angle of 3 deg. to 20 deg.; where a needle (38 or 38') is positioned at a distal end of the device, where a suture (34) is configured to move with the needle from a retracted position to an extended position, where a portion of the suture extends lengthwise from a tip of the needle toward a proximal end of the device and outside of

Art Unit: 3731

the needle (see fig. 11A) where the method includes inserting a sheath or sleeve (12) into a vessel, inserting a snare (42 and/or 40 and 74) and a needle (38) on a first side of a vessel opening, inserting a suture (34) and another needle (38') on a second side of the opening, grasping the suture with the snare, pulling the suture across the vessel opening (see fig. 11d), directing the distal end of the suture through a pre-tied knot (80) at a proximal end of the suture, cinching the knot or tightening the suture, disengaging and withdrawing the sheath (12) from the vessel opening; where the device is secured in the blood vessel (via 24), where the sheath is anchored in the vessel with a pair of extendable feet (24a and 24b or 22 and 24), and where a safety wire (GW) can be inserted into the vessel opening and be used to facilitate reinsertion of the sheath.

3. Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al. (5,728,114). Evans et al. disclose, at least in figures 7-12 and in col. 7, line 28 to col. 8, line 20; a vascular closure device including an anchor (22) configured to extend through an opening in a blood vessel, the anchor being configured to move between a contracted configuration (see fig. 10), where the anchor is sized to fit through the opening in the blood vessel and expanded configuration (see fig. 11) where the anchor is too large to fit through the opening in the blood vessel, a snare (42) configured to be inserted through a wall of the blood vessel at a location that is adjacent to the opening in the blood vessel (within the blood vessel); a suture (24) configured to be inserted through the wall at another location adjacent the opening, the snare also being configured to grasp the suture in the blood vessel and retract the suture through the wall of the blood vessel, where the device is configured to close the opening in the blood

vessel (see figs. 9-11), where the snare comprises a wire loop (42) having a memory that causes the loop to open in a repeatable orientation (i.e., the loop is flexible), where the snare and the suture each move between a retracted position and an extended position to allow the snare and the suture to be inserted through the wall of the blood vessel (from within the blood vessel), and where the device further comprises a handle set (26 and 28) to allow an operator to control movement of the snare and the suture.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riza (5,562,688) in view of Goldrath (5,330,488), and further in view of Kammerer (5,562,684). Riza discloses the invention substantially as claimed. Riza discloses, at

Art Unit: 3731

least in figure 5, a device including a needle movable between retracted and extended positions with respect to a tubular housing (11), a suture (81), and a snare (84) configured to move with the needle, where the snare comprises a wire loop (84) having a memory as claimed. However, Riza does not disclose another needle configured to be movable between retracted and extended positions with respect to the tubular housing (11) and a suture movable with another needle between retracted and extended positions, where the suture proximal end includes a pre-tied knot.

Nevertheless, Riza discloses, in col. 8, lines 25-28, that elongated tools may be inserted into the tubular housing for manipulation of suture. Goldrath teaches, at least in figures 2 and 6, an elongated tool or needle (40) for manipulation of suture. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Goldrath, to apply a needle for carrying and manipulation of a suture in the Riza's device. Such a needle would allow the guidance of suture into relatively inaccessible or closed surgical sites, where a suturing procedure can further be more performed with the use of a snare as disclosed by Riza (and as also taught by Goldrath). Moreover, Kammerer teaches, at least in figures 16-25 a suture (100) with a pre-tied knot (102) on its proximal end. It also would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kammerer, to include a pre-tied knot with the suture of Riza's device. Such a knot would allow a quick and convenient means for tying and tightening a suture around tissues to be joined together.

***Response to Amendment***

6. The rejection of claims under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, is hereby withdrawn.

With respect to arguments regarding the rejection of claims under 35 U.S.C. 102 and based on the reference of Modesitt et al.: Modesitt et al. indeed disclose the elements recited in the claims. Specifically, a portion of suture 34 (not 74) qualifies as the suture recited in claims 1, 7, 13, and 24, because it does move with a needle (38 or 38') from a retracted position to an extended position, and it is inserted through the wall of the blood vessel (from within the blood vessel) at a location adjacent to the opening or on a second side. Modesitt et al. also disclose, at least in figure 11A, a portion of suture 34 that is "outside of the needle."

The rejection of claims under 35 U.S.C. 102 and based on the references of Riza and Burbank et al. is withdrawn, in view of new grounds of rejection.

With respect to arguments regarding the rejection of claims under 35 U.S.C. 103 and based on the references of Riza, Goldrath, and Kammerer: The Examiner disagrees with the Applicant's contention that a pre-tied knot, if used with the trocar gripper (10) of Riva, would "serve to suture the trocar gripper 10 to the opening in the patient." On the contrary, the pre-tied knot, as taught by Kammerer, is applied with a surgical port having an opening, where the pre-tied knot is separate from (i.e., not tied to) the port, and where the port is analogous in structure and function to the trocar gripper of Riza. The pre-tied knot in Kammerer does not serve to suture the port to an opening in a patient, and in analogy, a pre-tied knot applied in the device of Riza would not serve to suture the trocar gripper to the opening in the patient.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for




Art Unit: 3731

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Julian W. Woo". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

Julian W. Woo  
Primary Examiner

October 2, 2007